BACKGROUND STUDY PAPER NO. 8

April 1999

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COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

ACCESS TO PLANT GENETIC RESOURCES AND INTELLECTUAL PROPERTY RIGHTS

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This background study paper was prepared at the request of the Secretariat of the FAO Commission on Genetic Resources for Food and Agriculture, to provide a theoretical and academic background to questions of access to plant genetic resources and intellectual property rights. The study is the responsibility of the author, and does not necessarily represent the views of the FAO, or its Member States.

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For reasons of economy, the paper is available only in the language in which it was prepared.

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INTRODUCTION

The importance of the conservation and sustainable utilization of plant genetic resources for food and agriculture is broadly recognized today. The work by the FAO Commission on Genetic Resources for Food and Agriculture, and of many national and international institutions, experts and NGOs, has contributed to identify a number of actions that are necessary and urgent at national and international level to prevent genetic erosion and to foster a sustainable agriculture[1].

One of the areas for global action relates to on farm conservation. Farmers not only use seeds; they are key players in the process of the conservation and improvement of plant varieties. Their activities ensure crop evolution whereby new types of varieties arise through genetic recombination, mutation, and hybridization within and between cultivated and wild plant populations (Brush, 1994, p. 7).

The present and past contributions of farmers to plant diversity have been recognized by the International Undertaking on Plant Genetic Resources. Current negotiations to define the content of "Farmers Rights", in particular, have highlighted several areas in which action would be required in order to preserve the process of on-farm conservation and integrate it with other forms of conservation.

In addition, such negotiations have confirmed the importance of ensuring, at least for a number of crops, a regime that facilitates access to and the exchange of plant genetic resources, a key issue in the International Undertaking on Plant Genetic Resources, as originally adopted. Such access and exchange have so far been one of the bases of the continuous progress in agriculture world-wide. In every country, most of the germplasm used in agriculture comes from other countries, and it is often very difficult or extremely costly, and sometimes practically impossible, to determine the country of origin. Any region of the world is dependent on genetic material which originated in other regions for over 50% of its basic food production, and, for several regions of the world, this dependency is close to 100%.

The Convention on Biological Diversity (CBD), on the other hand, has stressed the importance of *in situ* conservation, and established rules on the access to genetic resources and on benefit sharing, in the context of States' sovereignty over such resources[2].

In parallel with the recognition of the role of farmers, and of the relevance of the conservation and transborder flows of plant genetic resources, the issue of protection of intellectual property rights (IPR), including in plant materials, has become an important item in international negotiations. Article 27.3 (b) of the TRIPS Agreement,[3] in particular, requires the provision of protection for "plant varieties", under intellectual property rights.

The International Undertaking had recognized (FAO Resolution 4/89) that plant breeders' rights were not incompatible with its objective of furthering access to, and sustainable use of, plant genetic resources for food and agriculture. At the time this resolution was adopted, the prevailing

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1 See, in particular, the Report of the Leipzig Conference on Plant Genetic Resources.

2 For an analysis of the CBD, see Lesser, 1998.

3 Agreement on Trade-Related Aspects of Intellectual Property Rights.

model of plant breeder's rights (PBR), as epitomized by the UPOV[4] Convention, 1978 Act, clearly permitted the use of protected varieties as the source material of further variation and the re-use of saved seeds by farmers, both important mechanisms of diversity generation. Since then, however, the revision of the UPOV Convention in 1991 and, particularly, the growing acceptance of patents on plant materials, including genes, have changed the legal framework in which on-farm conservation and germplasm exchange are to take place.

The way in which those three instruments, the TRIPS Agreement, the UPOV Convention and the CBD, are implemented will influence the development and operation of any multilateral system on PGR for food and agriculture. An important issue is, therefore, to what extent and how the objectives and principles of said instruments may be compatibilized among themselves and with the objectives and principles of a revised International Undertaking.

This paper discusses how the granting of IPR protection may affect the development of a multilateral system under a revised International Undertaking, based on the principles of "shared access", that is, access given in the framework of a system that ensures the sharing of benefits. It will try to elucidate the extent to which IPR affect the access to PGR for research and breeding, and if and how the objectives of the CBD and International Undertaking with regard to access to genetic resources may be made compatible with IPR legislation.

In particular, the paper examines the extent to which existing IPR, particularly patents, PBR and undisclosed information (trade secrets), may affect the principle of access, as it is being developed in the framework of the International Undertaking and the CBD. It also briefly examines the main trends with respect to the protection of plants and plant genetic resources, and discusses several elements of such regimes that may favour or block access to PGR.

I. FROM "FREE" TO "SHARED" ACCESS

The development and sustainability of agriculture are strongly dependent on access to plant genetic resources. Though there are important differences in their endowment of plant diversity, no country can claim self-sufficiency in this area. The global interdependency that prevails in respect of PGR explains why access to PGR is a cornerstone of international instruments dealing with PGR, particularly the International Undertaking and the CBD.

Article 5 of the International Undertaking, as adopted in 1983, stated that:

> "It will be the policy of adhering Governments and institutions having plant genetic resources under their control to allow access to samples of such resources, and to permit their export, where the resources have been requested for the purposes of scientific research, plant breeding or genetic resource conservation. The samples will be made available free of charge, on the basis of mutual exchange or on mutually agreed terms".

The CBD recognized sovereign rights over genetic resources and established new international rules on access, which is subject to the principles of prior informed consent and the sharing of benefits (articles 3 and 15).

One of the main objectives of the revision of the International Undertaking is to harmonize its provisions on access with the CBD's principles. Through negotiations are still in progress, current discussions suggest that, given the peculiar nature and global distribution of PGR, there is a basic agreement to develop a multilateral system of access and sharing of benefits for these resources.

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[4] International Union for the Protection of New Varieties of Plants.

Under such a system, access to PGR for food and agriculture would be allowed to all parties participating therein, who shall benefit from such access and from other elements in the system (access to research results, international funding, *etc*.).

This process shows the shift from a concept of "unrestricted" or "free" access, to a concept whereby access is promoted and facilitated, within the framework of a system for the sharing of benefits, which are available only to those parties participating in the multilateral system. The emerging concept is, thus, one relying on a principle of "shared access".

In the negotiation of the International Undertaking, one point seems to have remained clear: that access to PGR for food and agriculture is essential for a sustainable agriculture and should be ensured by any multilateral system to be developed.

As reflected in the debates in the FAO Commission on Genetic Resources for Food and Agriculture, and in various contributions, studies and statements by NGOs, concerns have been growing with regard to the extent to which IPR may jeopardize the exercise of sovereign rights over PGR, and make illusory the implementation of a balanced multilateral system, based on the principle of shared access.

These concerns have been accentuated by the expansive application of IPR, particularly patents, to living organisms and by the possibility, in most industrialized countries, of obtaining exclusive rights of exploitation with regard to genes, and any subcellular part of plants, as well as of plant cells, plant varieties and species. According to the view of two researchers,

"Neither genes nor plant varieties will be available for further development without the previous consent from the holders of intellectual property rights. In addition, biotechnological process of broad application in plant breeding, including techniques for screening, mapping and engineering genes, and methodologies for tissue culture, have been patented" (Miranda Santos and Lewontin, 1997, p. 5).

Diverging views on the likely impact of IPR on access to, and the use of PGR for food and agriculture, may jeopardize further advances in the development of a multilateral system on PGR for food and agriculture. Some countries may find it difficult to agree on a system of shared access, if the genetic resources maintained and developed by their farmers and communities may be appropriated under IPR by foreign companies, especially if such IPR may create barriers to access and use the protected material. This conflict has been described by V. Shiva and R. Holla-Bhar as follows:

> "The Third World farmer has a three-fold relationship with the corporations that demand a monopoly of life forms and life processes. Firstly, the farmers is a *supplier* of germplasm to TNCs.[5] Secondly, the farmer is a *competitor* in terms of innovation and rights to genetic resources. Finally, the Third World farmer is a *consumer* of the technological and industrial products of TNCs. Patents protection displaces farmers as competitors, transforms them into suppliers of free raw materials, and makes them totally dependent on industrial suppliers for vital inputs such as seeds" (Shiva and Holla-Bhar, 1996, p. 157).

The fears of a negative impact of IPR on sovereignty over, and access to, PGR has been exacerbated by current trends in the IPR protection of genetic resources.

First, a large number of patents have been granted on genetic resources obtained from developing countries, often without the knowledge and consent of the possessors of the resources (sometimes

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5 Trans-national corporations.

called "biopiracy"). There has been extensive documentation of IPR being sought over resources "as they are", without further improvement (e.g., US patent No. 5,304,718 on quinoa granted to researchers of the Colorado State University) and on products based on plant materials and knowledge developed and used by local/indigenous communities, such as the cases of the neem tree, kava, barbasco, endod and turmeric[6], among others *etc*. (Mooney, 1998, p. 152-154).

Second, some patents have been granted with a broad scope, thus limiting access to a wide segment of germplasm. In some cases, claims described in functional - rather than in structural terms[7] - have been accepted, with more or less latitude. In others, the claims cover the application of a technical solution to a wide range of undifferentiated germplasm, such as in the case of "species wide" patents. Examples of broad claims include an Agracetus patent referring to any genetic manipulation of cotton regardless of the germplasm in use; a patent granted to Plant Genetic Systems covering the introduction of Bt into most field crops, and a patent obtained by Lubrizol covering sunflower seed with a high oleic acid and a low linoeic acid content.

Third, some cases of PBR protection being sought over materials deposited in genebanks and held in trust for the international community have been identified. This has led the Consultative Group on International Agricultural Research (CGIAR) Secretariat to call for a moratorium on the granting on IPR over plant germplasm held in the collections of the CGIAR Research Centres around the world,[8] and designating as forming part of the International Network of *Ex Situ* Collections under the Auspices of FAO. It is the CGIAR's stated policy that such germplasm is held in trust for the world community and should not be subject to IPR, by the Centres, or the recipients of the materials[9].

Fourth, the protection by IPR of living materials, including plants, raises a number of ethical issues which, in the view of many authors and organizations, should be a sufficient basis to prevent any private party from obtaining exclusive rights on such materials[10].

The implications of IPR on access to, and use of, PGR for food and agriculture is not only a preoccupation in developing countries. Thus, according to the Director of the AgBiotech Centre of the State University of New Jersey, "

"in theory, the patent system is supposed to make material available for further research by protecting the interests of the patent holder. In practice, the patent holder can find many ways to block distribution of the patented materials and to limit the uses made of it" (Day, 1995, p.83).

One of the conclusions of a Workshop sponsored by several US organizations and the US Department of Agriculture in 1993, was that the patenting of plant materials may interfere with the exchange of materials among researchers and among government, university and private laboratories (CCSA, 1993, p. 5). In a follow-up Seminar held on the same issues four years later,

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6 A patent on turmeric granted to the University of Mississippi Medical Centre in December 1993, was recently invalidated by the US Patent Office upon request of the India's Council for Scientific and Industrial Research.

7 This means that the invention is described on the basis of what *it does* rather than defining what *it consists of.*

8 See CGIAR Press Release, 11.2.98.

9 See Guiding Principles for the CGIAR Centres on Intellectual Property and Genetic Resources, 1996.

10 For a discussion on ethical issues, see Macer, 1990.

one of the Work Groups recommended, more specifically, "full and open access to genetic materials" and that

> "the appropriate standards for utility patents be reconsidered...in light of the potential for serious impediments to effective research and genetic resource use, especially in the public sector in countries with limited economic resources" (CSSA, 1998, p. 109).

II. Access to PGR under Patent Laws

Plant biotechnology patents

The number of patents on biotechnological inventions has significantly grown since the first grants at the end of the seventies. Between 1990 and 1995, around 25,000 biotechnological patents were granted throughout the world. The annual number of such patents represented about 1% of the total number of patents granted per year, world-wide.

Table 1
Origin of Biotechnology Patents

Country of origin	Total per country No.	Total per country %
United States	5,775	35.4
Japan	5,706	34.9
EPO[11] Countries	2,903	17.8
Rest of Europe	268	1.6
Australia	181	1.1
Canada	94	0.6
China	173	1.1
Israel	70	0.4
Republic of Korea	119	0.7
Other Countries	103	0.6
Total per Country	16,327	100

Source: CEFI, 1997

As indicated in Table 1, around 35% of biotechnology patents originated from the United States, in 1990-1995, and a similar percentage from Japan. The European Union accounted for about half that percentage (18%) in this period. It is to be noted that all other countries together, including *all developing countries*, only accounted for 6% of total patents granted in said period. This is one indicator of the dramatic North-South asymmetry with regard to the innovative capabilities in modern biotechnology (Correa *et al*., 1996).

Patents relating to agriculture represented 11% of the total for 1992-1995, and those specifically covering modified plants, 6% of the total.

Table 2 contains a list of the enterprises and institutions most active in the field of plant patents, between 1992-1995. Of the 16 listed, only five were of the US origin, but they accounted for 46% of total plant patents, that is, 11% more than the average for all biotechnology patents indicated above.

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[11] European Patent Organization.

Table 2
Most active applicants for patents on plants, 1992-1995

Applicant	Country	Number
Pioneer Hi-Bred International	United States	70
Zeneca/ICI	United Kingdom	50
Monsanto CO.	United States	28
Sandoz	Switzerland	24
Calgene	United States	23
Holden´s Foundation Seeds	United States	23
Max Planck Gesellschaft	Germany	19
Ciba Geigy AG	Switzerland	17
Hokko Chemikal Industry	Japan	16
Dupont de Nemours	United States	15
Mitsui Toatsu Chemicals	Japan	14
Plant Genetic Systems	Belgium	14
Hoechst-Schering Agrevo	Germany	13
Japan Tobacco	Japan	13
Mitsubishi	Japan	12
Mogen International	Netherlands	12

Source: CEFI, 1997.

The fact that the sixth most active applicant is a public research institution in Germany[12], suggests the special link existing between scientific and technological research in this field.

Do patents restrict access?

If a crucial aspect of a multilateral system on PGR for food and agriculture is, as mentioned, the possibility of accessing such resources for research and breeding, it is essential to clarify the extent to which existing patent regimes may affect such access.

Access to existing genetic materials is necessary for the continuous adaptation and improvement of plants for food and agriculture. A new plant variety cannot be created *from scratch*. In the field of plant development there is no actual "creation" (Vignoli, 1986, p. 205). The improvement of crops can only take place on the basis of the use and modification of what nature has created. Innovation in breeding activities is essentially of an "incremental" nature[13], in the sense that it progresses on the basis of successive changes on available varieties.

The granting of a patent entails the right to prohibition (*ius excluendi*) the use of the patented material in the countries where the rights have been recognized. According to article 28.1 (a) of the TRIPS Agreement, patents relating to products confer the right to prevent third parties not having the patentee's consent from "making, using, offering for sale or importing for those purposes the product".[14] In the case of process patents, the patentee may prevent the use of the process as well

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12 When all biotechnology patents are considered, and not only those relating to plants, among the 16 most active applicants are two US universities (California and Texas).

13 The distinction made by innovation theory between "major" and "minor", or "incremental", innovations is relevant here. See, for instance, Freeman and Perez, 1986.

14 While this provision expressly refers to the importation as one of the exclusive rights of the patent-holder, in a footnote to the same article a cross reference is made to article 6 of the

as the commercialization of a product "obtained directly by that process". Thus, if a process to produce a plant (*e.g.*, a transgenic plant) is patented, exclusive right would also apply with respect to the plants obtained with the process.

Given the territoriality of patent rights, the title holder cannot exercise his/her rights outside the jurisdiction where the patent has been registered. But he/she can prevent the importation of products made elsewhere containing the invention. This has been one of the main concerns, for instance, of Indian cotton producers in view of the patent on all transgenic cotton conferred on Agracetus (patent US 5,159,135), and of Andean farmers, with respect to the already mentioned patent granted to Colorado State University (US 5,304,718). A similar concern has raised more recently in the case of a US patent relating to an allegedly improved form of "Basmati" rice, which is normally grown in sub-Himalayan India and Pakistan[15].

The existence of a patent, thus prevents, the production or commercialization of any product containing the invention. For instance, if a plant variety is protected, it may not be possible to use the propagating material of that variety for commercial purposes, including for breeding new varieties. Similarly, if modified plant cells are patented, any plant containing those cells would infringe the patent.

In the framework of the International Undertaking and of the CBD, the key issue to be addressed is the use of a protected material for the purposes of improving it, for instance, by developing a new variety, rather than its use, *as such*, for production or reproduction. The first type of use is here called for "research and breeding" .

Patents on biological materials

Patent law has traditionally distinguished between "inventions", which are patentable, and "discoveries", which are not (Caforio, 1995, p. 60-64). This distinction has been blurred in some countries, however, with the advent of genetic engineering.

In the United States an isolated and purified form of a natural product is patentable. The concept of "new" under the novelty requirement does not mean "pre-existing" but "novel", in a prior art sense, "so that the unknown but natural existence of a product cannot preclude the product from the category of statutory subject matter" (Bent et al, 1991, p. 123).

Under the rules of the European Patent Office, a patent can be granted when a substance found in nature can be characterized by its structure, the process by which its is obtained, or by other criteria, if it is new, in the sense that it was not previously available to the public. In the European Directive on the Legal Protection of Biotechnological Inventions (98/44/EC of 6 July, 1998), it is clarified that

> "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature" (article 3.2).

Similarly, in Japan, the Enforcement Standards for Substance Patents, stipulated that patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance could not be detected without prior isolation with the aid of physical or chemical methods. The new Guidelines of the Japanese Patent Office on Biotechnological Inventions

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Agreement, which allows Members to allow for "parallel imports" under the principle of international exhaustion of intellectual property rights.

15 See SUNS # 4175, 19.3.98.

(February 1997) allowed freer expression formats in the description of claims than the 1993 Guidelines do, and removed some limitations on claims drafting, such as the obligation to restrict patent claims essentially to a single specific sequence (Okuyama, 1997, p. 8).

A comparative study on "Biotechnology Patent Practices"[16] of the Patent Offices of USA, European Union and Japan indicates that the differences with regard to the patenting of biological materials have significantly narrowed in those jurisdictions.

On the basis of these developments, numerous patents have been granted relating to biological materials taken from humans, animals and plants in industrialized countries. In particular, in many jurisdictions, the patenting of genes has become a common practice. Claims in these cases normally refer to an isolated DNA sequence, DNA constructs and new transformed plants derived from them. Claims often include natural DNA sequences without limitations.

Patents covering genes are not generally confined to the sequence of a gene. The patent application typically claim: first, a gene or protein, standing alone, corresponding to that sequence; second, a vector or plasmid incorporating the sequence; and, possibly, third, an organism (*e.g.*, a plant) that has been transformed by means of such a vector. Thus, the patent holder gains effective control over the use of the specified gene in genetic engineering (Barton, 1993, p. 14).

Some developing countries, however, do not go so far with regard to the patentability of existing biological materials. Thus, the Mexican law excludes the patentability of all genetic materials. The Argentine patent law, and the Andean Group Decision 344, do not allow the patentability of materials existing in nature. The Brazilian patent law (1996) stipulates that no patents shall be granted with respect to living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being.

Patents on genes

Patent claims in the plant field may refer to a variety of materials and processes, such as:

* DNA sequences that code for a certain protein;
* isolated or purified proteins:
* plasmids and transformation vectors containing a gene sequence;
* seeds;
* plant cells and plants;
* plant varieties, including parent lines[17];
* hybrids;
* processes to genetically modify plants; and
* processes to obtain hybrids.

Patents are normally granted with respect to isolated genes in some countries, where the mere fact that there has been isolation of a gene with a defined function is deemed sufficient ground to confer a patent, even if the protein that it codifies has been previously known[18]. The US Patent and Trademark Office, for instance, has issued numerous patents to isolated and purified forms of

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16 As a component of the Trilateral Project 24.1- Biotechnology.

17 Patents have been granted on the basis of claims relating to phenotypic characteristics, or to a combination of phenotypic and genotypic characteristics. Thus, a trait that has been identified or bred into plant lines may be claimed either phenotypically or genotypically.

18 This is explained by the fact that a specific protein is not encoded by a single DNA sequence, but by a large number of synonymous sequences (Vossius, 1997, p. 17).

naturally-occurring DNA molecules *as such*. The only condition is that they must be claimed in a non-naturally-occurring form, *e.g.*, as an isolated or purified molecule.

Processes involving the manipulation of genes may be based on the use of genomic DNA, a natural substance, or of cDNA, that is, a DNA copy of mRNA, that does not exist as such in nature. Patentability may proceed in both cases. In the United States, the Court of Appeals for the Federal Circuit has affirmed the validity of claims to full length DNA or genomic DNA molecules such as, in the pharmaceutical field, of the cases of erithropeietin, insulin and human growth factor (Tribble, 1995, p. 100). The US Patent and Trademark Office issued a patent in favour of Plant Genetic Systems NV covering the full length *cry1Ab Bacillus Thuringensis* (Bt) gene.[19]

Claims relating to genes may be described by specifying their base sequences. Nevertheless, a description based on a combination of the gene's function, physical and chemical properties, origin, source or production process, may be acceptable as well. Thus, in USA, European Union and Japan, claims that do not structurally describe the sequence of DNA, but the amino acid sequence of a protein encoded by the gene[20], are admitted.

Genes in plants, as mentioned, are often claimed in conjunction with a purified protein, plasmids and transforming vectors, and plants or seeds. The patenting of genes at the cell level extends the scope of protection to all plants which include a cell with the claimed gene. Box 1 provides some examples of patent claims relating to the use of *Bacillus Thuringensis* to generate plant resistance to certain insects.

BOX 1 . EXAMPLES OF PATENT CLAIMS ON BT GENES

The invention relates to a chimeric gene which, in the cells of cotton plants, expresses insecticidal compounds which essentially have the insect-toxic properties of the crystalline protein produced by Bacillus Thuringensis. The transformed cells are regenerated to complete plants which are toxic to the larvae of insects from the orders *Lepidoptera*, *Coleoptera* and *Diptera* (Ciba-Geigy AG, EP 0317511).

A DNA fragment, encoding all or an insecticidally-effective part of a Bt crystal protein, is modified by changing A and T sequences to corresponding G and C sequences encoding the same amino acids (Plant Genetic Systems N.V, WO 9116432; EP 9100733).

A plant cell transformed with a *Bacillus thuringiensis* gene coding for a protein of at least 66 kDa that is toxic to Coleoptera. A plant containing the transformed cell is resistant to *Coleoptera*.

In countries where the patenting of genes is admitted, an important issue is, therefore, the scope of the exclusive rights that the title-holder may exercise with regard to the use of the gene by third parties. In particular, a crucial issue in the plant field - relevant to the implementation of any instrument on access to plant genetic resources - is the extent to which the patentee may prevent the use of a recombinant gene, as well as of the gene in its natural form.

According to one opinion, patents on genes protect the patent holder "against use of the gene by another biotechnologist, but leave anyone free to use and breed with organisms containing the gene naturally" (Barton, 1997, p. 1). Thus, the patent would prevent a third party from crossing the

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19 AgBiotech, 1997, vol. 9, No. 11, p. 252N.

20 For instance, "a gene encoding a protein having an amino acid sequence of Met-Tyr...-Cys-Leu" (Japanese Guidelines for Biotechnology Inventions, February 1997).

inserted gene into a different variety and marketing it,[21] but not to develop, by conventional breeding methods, a variety that includes and expresses the natural gene.

This would imply that if a gene is identified in a plant and subsequently patented in a country, breeders may still use the natural gene in breeding activities (Heitz, 1991, p. 21), but the use of the isolated gene to develop transgenic plants may be restricted by the patent holder in that country, till the expiration of the patent. Hence, the conventional way of utilizing the natural gene may be unrestricted for research and breeding.

This interpretation seems to find, in principle, support in the doctrines and legislation of some countries. In the United States, a natural DNA sequence has been deemed "free to all men and reserved exclusively to none", despite that the claim on a "purified and isolated" DNA sequence was clearly considered as patentable subject matter (Amgen Inc. v. Chugai Pharmaceutical Co.).[22]

The previous UK patent law (article 4.7) included a "disclaimer", according to which claims did not extend to a product, "when found in nature". This was also the position of German courts, in some decisions; however, some authors contend that the protection conferred by a patent should extend to the natural substances, if covered by the claims (Bergmans, 1991, p. 278).

Patenting principles and practices on biotechnological inventions are still in a state of flux, including in those countries that have already gained experience in the patenting of genes. The extent to which a patent on an isolated gene may extend to genes existing in nature may be subject to different interpretations[23] under national laws, and over time. Patent holders may not quietly consent that breeders put a (protected) gene into a variety that would ultimately compete with the patentee's own variety. As noted by a member of the plant biotechnology industry

> "many patents are still pending...and represent an uncertainty. Indications from the first products being commercialized in cotton, corn and soybean suggest that patents are being aggressively enforced and are being used to establish competitive advantage in the marketplace" (Evans, 1996, p.75).

Even if courts may finally limit the patent rights to non-naturally occurring substances[24], the threat of litigation[25] may deter innovation and effectively block or reduce the use of germplasm for research and breeding[26]. According to Miranda Santos and Lewontin,

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21 Prof. Day has documented the problems faced by his university team when they tried to use the **bar** gene in a turf grass species to confer herbicide resistance. The gene had been patented as a selective marker for the laboratory, for recovering products of transformation, and for field use to confer herbicide resistance (Day, 1995, p. 81).

22 13 USPQ2d 1737, 1759 (D. Mass. 1989).

23 According to Crespi, for instance, patents on genes should "have the same legal effect as other patents for chemical compounds and should therefore extend to all compositions containing them and to all uses to which they are applied to exploit their properties" (Crespi, 1988, p. 114).

24 In Europe, for instance, defendants may argue that natural genes are the result of "essentially biological processes", which are not patentable.

25 The extension of patents to living materials has given raise to a high number of contradictory procedures before patent offices and to substantial litigation in courts, notably in the United States and Europe. Plant-related patents have been responsible for a good part of this turmoil (Barton, 1997, p. 6-15).

"patents on genes of wide utilization in agriculture can block the development of new varieties in a clear contradiction to the objectives for which the (patent) system was designed" (Miranda Santos and Lewontin, 1997, p. 5).

Patents on varieties

Patents on plant varieties are accepted in some countries, such as the United States[27] and Australia[28]. There are several examples of patents granted with respect to plant varieties in the United States (see Box 2).

Box 2 . Examples of patents on plant varieties

"An inbred corn line having the designation AI"
(US Patent 4,594,810, Claim 1)

"Novel soybean varieties CX174" (US Patent 4,626,610, Claim 7)

"A new and distinct plant variety, Yensen 3a, of **Distichlis palmeri**, ..."
(US Patent 4,762,964, Claim 1)

"Inbred corn seed designated PHN73 having ATCC Accession No.75205."
(US Patent 5,157,208, Claim 1)

"Novel F1 generation hybrid corn seed DK672"
(US Patent 4,607,453, Claim 2)

"F1 generation hybrid corn plant DK524"
(US Patent 4,629,819, Claim 1)

Source: Seay, 1993, p. 69.

The examples in the Box show that varietal protection is also available for F1 hybrid plants and for inbred plant lines. Hybrids may also be claimed simply by designation.

The UPOV Convention, as revised in 1978, banned the accumulation of PBR with patent protection for one and the same botanical genus and species. This restriction was in line with the European Patent Convention, which prohibited the patenting of both "plant varieties" and "animal races" (article 53 b) of the Convention).

Though the prohibition of the European Patent Convention remains in force, the proposed Directive on the Legal Protection of Biotechnological Inventions, is likely to limit the scope of the

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[26] See also Plowman, 1993, p. 35. On the use of "strategic litigation" to prevent competition, see Barton, 1995, P. 163.

[27] This form of patent has not yet been tested in courts in the United States (Barton, 1998, p. 25).

[28] Mexico admitted patents on plant varieties in its law of 1991, but the patentability of plant varieties was excluded in 1994, when the law was amended as part of the process of accession to the North American Trade Agreement.

exclusion. It stipulates that "inventions which concern plants or animals may be patented if the application of the invention is not confined to a particular plant or animal variety (article 4.2), and that "the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material...in which the product is incorporated and in which the genetic information is contained and expressed" (article 9)[29].

The approach of the European Patent Convention has been followed in the legislation of many other countries as well. Thus, Brazil has enacted PBR legislation in 1997 that is reported to prohibit patents on plant varieties (article 2)[30]. Patents on plant varieties are also excluded in Argentina (Decree 260/96).

While the requirements to obtain a patent are more strict than for a PBR (in the latter case it is not necessary to prove that the variety is novel and "non-obvious"), the legal powers conferred to the patentee are broader than those granted to the PBR title holder. Hence, though the number of patented plant varieties may be much less than those under PBR, such varieties will be subject to more severe restrictions, particularly with respect to access for research and breeding.

In most patent laws, in effect, there is no exception similar to the "breeders exemption" under PBR. Hence, the patentee may, in principle, prevent a third party from using the patented variety for further research and breeding. He could prevent, for instance, multiplication of the variety, even experimentally, tests crosses and any subsequent research and development with the crosses made (Roberts, 1996, p. 533), as well as the use of the material as the parent of another variety, unless the patent claims do not cover such a use (Barton, 1998, p. 26).

Since a plant variety "is characterized by essentially all of its genes" (Roberts, 1996, p. 535) the patenting of plant varieties may restrict the access to and use of the whole combination of genes that constitutes a variety, and prevent the development of new combinations of such genes. Moreover, according to one view, such a restriction would not only apply to the overall genetic structure of the protected variety, but also include "isolated traits or genes embodied in it" (Miranda Santos and Lewontin, 1997, p. 5).

Patent laws may, however, provide for certain exceptions and mechanisms that limit the patentee's rights with regard to research and breeding, such as by allowing for experimental uses, as discussed below.

Can patents and access for research and breeding be reconciled?

The previous section has indicated that patents, in principle, prevent third parties from acceding to the protected materials for research and breeding purposes. This effect is particularly strong when patent claims are broadly drafted. The recognition of patents on plant materials may, therefore, restrict access to plant genetic resources in a manner incompatible with a multilateral system of shared access to, and benefit-sharing from, plant genetic resources, unless specific conditions are established for patenting in this field.

29 In one case the Board of Appeal of the European Patent Office had held that patent claims on genetically modified plant cells could not extend to seeds and cells, since protecting the latter would amount to patenting a "plant variety" (Plant Genetic Systems/Glutamine synthetase inhibitors, T356/93).

30 According to this article, PBRs are "the only form of protection on plants or their parts" available in Brazil.

This section examines whether, and to what extent, that incompatibility may be overcome, or attenuated, by designing a patent regime that specifically address the issues relating to the control and use of PGR. This can be achieved in a straightforward way if patents are excluded in the plant field, totally or partially. As examined below, such exclusion is allowed under the TRIPS Agreement.

If such exclusion is not provided for, the extent to which the access to a patented material for research and breeding would be subject to the patent-holder authorization's depends on:

a) the scope of the claims;

b) the interpretation given to the claims;

c) access to samples of the patented material;

d) the exceptions to the exclusive rights recognized by the national law, particularly for experimentation;

e) the availability of compulsory licenses;

f) the possible revocation of a patent, when the applicant fails to demonstrate compliance with certain aspects of relevant laws and regulations. These issues are briefly examined below.

Exclusions from patentability

a) Substances existing in nature

Nothing in the TRIPS Agreement or in other international conventions on IPR, obliges World Trade Organization (WTO) Member countries to follow an expansive approach in respect of the patenting of substances existing in nature, such as genes, cells, or plants as such. In effect, the TRIPS Agreement specifies the *requirements* that an invention must meet in order to be patentable, but it does not provide a definition of what an *invention* is. This leaves WTO Member countries free to determine what should be deemed an invention. Many laws in developing countries (*e.g.*, Argentina, Brazil, the Andean Group) exclude the patentabilty of materials found in nature, even if isolated.

An exclusion of this type (for instance, on the entire range of sequence variation that occurs in nature for any gene)[31] would solve part of the access-related problems mentioned above. The exclusion may ban the patenting of genes, cells or any other subcellular part found in nature, or isolated therefrom.

It should be noted that, though the TRIPS Agreement requires that "micro-organisms" be protected, nothing would prevent WTO Member countries applying the scientific definition of "micro-organism" (limited to viruses, algae, bacteria, fungi, and protozoa), rather than any microscopic life form which is accepted by institutions for the deposit of micro-organisms.

b) Plants

Moreover, the TRIPS Agreement specifically allows for the exclusion of the patentability of "plants", without referring to any specific classification thereof. Countries may exclude the patentability of plant species and varieties (including hybrids and transgenic plants), as well as their cells and seeds. It should be noted that if patents are granted on "plants", the protection may extend to a large number of plant varieties that incorporate the features on which protection is grounded.

Clearly, though plant varieties need to be protected by IPR, as discussed in other part of this document, there is no obligation to do this under patents.

c) Processes

Another possible exclusion relates to "essentially biological processes for the production of plants or animals". This concept, inspired by European law,[32] has generated considerable debate (Bergmans, 1991, p. 96).

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31 See Miranda Santos and Lewontin, 1997, p. 7.

32 More precisely, by Article 2 (b) of the Strasbourg Convention on European Patents.

The notion of "essentially biological" has been defined by the European Patent Office according to the degree of "technical intervention"; if the latter plays an important role in the determination of, or control over, the results, the process may be patentable (Guidelines for Examination of the EPO, No. X-232.2).

Under this notion, classical breeding methods are not patentable.[33] In contrast, methods based on genetic engineering (*e.g.* the production of a "transgenic" plant) where the technical intervention is significant, would be patentable.

d) Exceptions based on morality/*ordre public*

Article 27.2 and 3 of the TRIPS Agreement specify the exclusions to patentability that any country may (but is not obliged to) establish in its domestic law. Various ways are envisagable in which Member countries might not grant patents,[34] based on this provision.

The exclusion of inventions which are contrary to *ordre public* or morality, or similar grounds, is provided for in most patent laws. Both concepts are relative to the values prevailing in a society. They vary between cultures and countries, and change over time. Some important decisions relating to patentability may depend on judgements about morality, as illustrated by the case of the Harvard "oncomouse".[35]

The morality issue was treated by the European Patent Office in relation to the patentability of a herbicide-resistant plant. The patent being opposed related to herbicide resistant plants. The opponent argued that risks in connection with release of the plants into the environment were impossible to predict accurately, and therefore that a potential risk to mankind existed. "This argument was rejected", explained the Director of the European Patent Office, "because it was not considered appropriate to carry out the balancing exercise of the Harvard Oncomouse decision. The reasons given for this were manifold, but were primarily the lack of consensus in society on "objective morality", and the inability not only of the opponents but of all experts to prove the extent of the risks" (Gugerell, 1996, p. 97).

Patentability requirements

An important issue is how "novelty" and "inventiveness" (or "nonobviousness") are interpreted. There are some important differences in national legislation in this regard. For instance, in the United States the divulgation of an invention outside the country, which has not been made in a written form, is not admitted as destructive of novelty (section 102.a), 35 USC). This is one of the reasons why materials used by farmers and communities outside the United States, have, in some cases, been declared eligible for patent protection.

There are often differences in the way different patent offices judge novelty requirements, particularly with regard to the extent that the previous knowledge of a substance may prevent the granting of subsequent patents relating to the same matter. For instance, the Australian Patent Office withdrew patent rights (conferred to Hoffman-LaRoche) on the thermostable enzyme tag DNA polymerase in its native form, based on precedents in "prior art" that had not been admitted by the EPO.[36]

Similarly, how the existence of an "inventive step" is determined will define the scope of the possible protection. This is a quite difficult issue in the case of applications relating to plants. In one case (*Ex parte* C, 27 USPQ. 2d. 1492),[37] the Board of Patent Appeals and Interferences of the US Patent and Trademark Office did not accept the difference from previous varieties as sufficient to demonstrate nonobviousness. The court stated:

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33 In the Lubrizol case, however, the EPO admitted the patentability of a method to obtain hybrids.

34 Article 27. 2 states that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law".

35 The patentability of the oncomouse was rejected by the examiner at the European Patent Office (EPO) on morality grounds. This decision was reversed by the EPO Technical Board.

36 See *Nature*, vol. 390, 27.11.97.

37 Quoted by Barton, 1998, p. 25.

"We have reviewed the data and the declaration but are unpersuaded of patentability because there is nothing of record which explains why the differences between the claimed variety and a rot resistant variety such as "Pella 86" are so significant and unexpected that they should weigh more heavily than the numerous similarities between the claimed variety and the varieties of the cited prior art".

Claims scope

If patents on plant materials are allowed, a careful consideration should be given to the types of claims that are acceptable. This is an area where countries are not limited by international rules. For instance, till recently, Japan only accepted claims that stated the purpose, constitution and effect of the invention. In the case of genes, only claims based on a description of a specific base sequence were admitted (Okuyama, 1997, p. 7).

As mentioned above, claims that describe function rather than structure have been widely accepted in some countries. The admission of functional claims broadens the scope of protection to any means that performs the claimed function. Functional language in patent claims is often the source of considerable controversy and litigation (Taylor, 1997).

In an intermediate position, the use of functional claims may be accepted, for instance, only in cases where the description of the invention is otherwise impossible, along the lines of the European practice on the matter.[38]

Claims interpretation

Another component of the patent law that in practice determines the scope of the rights conferred to the patentee, is how non-literal infringement is judged.

The extent to which a given product (or process) is infringing, is generally judged literally, comparing the possible infringing product (or process) with the one claimed, as expressly described in the patent. In many cases, however, there may be no "literal" infringement (*e.g.*, there may be differences in the means used by the patentee and the possible infringer), but a court may find that the alternative embodiment of the invention is "equivalent" to the protected invention.

Different versions of the "theory of equivalents" allows for more or less room to improve on, and develop around, a patented invention. A strict construction of claims and a narrow doctrine of equivalents expands the field available for competitors to work around, improve, or adapt protected inventions (UNCTAD, 1996, p. 33).

At least one case has already been decided in which the "theory of equivalents" has been applied to a patent covering genetic materials. The Osaka High Court decided (in Genetech vs. Sumitomo Pharmaceuticals, March 1996) that the change at only one position in a sequence of more than 500 amino acid residues of tissue plasminogen activator (TPA) was an "equivalent" to the patented invention.

Important questions arise with regard to the scope of the protection conferred by a (utility) patent on a plant variety. While under PBR, varieties should be distinguishable by at least one clear feature, there are no specific rules with respect to patents. When may a patented variety be deemed an "equivalent" to the protected one?

The principles of the "theory of equivalents" may be inadequate to judge these cases, since the development of a new variety through breeding methods usually does not involve any "inventive step", and may, hence, be considered an obvious variant of the patented variety.[39] A more narrow interpretation hence may be necessary in such cases, as illustrated by the decision in Imazio Nursery Inc. v. Dania Greenhouses, where the US Court of Appeal for the Federal Circuit established that, in order to determine infringement of a plant patent,[40] it was necessary to prove that the accused plant had been derived from the patented plant, *i.e.*, that the former is an actual copy of the latter (Gioia, 1997, p. 516).

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38 See Decision T 68/85 of the EPO Technical Board.

39 For an interesting discussion on the application of the "theory of equivalents" and its implications on technical progress, see Merges and Nelson, 1996, p. 120-144.

40 Plant patents are conferred in the United States under the Plant Patent Act of 1930 for asexually reproduced plant varieties (excluding tuber propagated plants). Different principles of interpretation might apply in the case of utility patents..

Access to samples of patented materials

In order to comply with the disclosure requirement of patent law, the description of a biotechnological invention generally needs to be supported by the deposit of samples of the material that contains the relevant information.

Legal systems considerably vary on this topic. Under US law, access can only take place after the granting of the patent. Generally, the commercial use of the sample will amount to an infringement of the patent, but experimental uses are allowed. Under European law, samples may be obtained after publication of the application through an independent expert and for experimental purposes only.

National legislation may determine how to deal with the conditions of access to the deposited samples and, particularly, when and under which circumstances samples may be obtained by third parties. The Budapest Treaty - which establishes an international system for the deposit of biological materials - is based on the assumption that access to the sample will be granted after publication of the relevant application (Rule 11.3 (a) of the Regulations of the Treaty). The access to samples after such publication may accelerate innovation based on improvements of the protected invention or the development of new inventions.

Access to deposited samples may, however, be problematic. As noted by a researcher,

> "even after the patent is filed and granted, access to the material can be denied by failure to answer requests. Such access as may be granted may not be meaningful since profitable use of the materials may be prohibited and, even if allowed, is subject to restrictions. The result is that the laws sometimes limit, or even prevent, beneficial applications" (Day, 1995, p. 83).

It should be noted that the failure to supply deposited samples, or the lack of correspondence between the claimed and the deposited material, may result in invalidity of the granted patent (Correa, 1994a, p. 20).

Experimentation exception

A crucial issue that may affect access for research and breeding is the extent to which an invention may be used for experimentation purposes. Some patent laws admit exceptions to the title-holder's exclusive rights with regard to the *experimentation* on the invention. However, the scope of the exception significantly varies in different countries.

In the United States, the exception is not a part of the patent statute. It has been created by case law, but in rather narrow terms. Experimentation is admitted for "philosophical" (*i.e.*, "scientific") purposes, and to create *other* products outside the scope of a patent (Wegner, 1994, p. 458). If restrictively interpreted, this exception is not likely to entitle a third party, for instance, to cross patented seeds to produce improved varieties.

In Japan the research exception is expressly provided for under the patent law, article 69(1) ("The effects of the patent right shall not extend to the working of the patent right for the purposes of experimentation or research"). In Europe, experimentation *on* the invention (as opposed to *with* the invention), even for commercial purposes, is generally considered legitimate.

Experimentation on the invention may be undertaken, for instance, to test an invention, to determine its sufficiency or compare it to prior art; to determine how the invention works; to improve on or develop another invention; to "invent around", or to test the invention, before requesting a license.

The scope of the exception is particularly ambiguous in the biotechnology field, for instance, with regard to the use of cDNA sequence information to produce a certain protein. Such a use is likely to be deemed illegal in the United States, while it is unclear whether it would be acceptable under the "research exception" in Europe and Japan (Wegner, 1994, p. 458-459).

Patent scholars have supported, however, the recognition of such exception on broader terms, so as to further technological development, on the basis of protected inventions (Wegner, 1994, p.456). The need for an experimentation exception is particularly felt in sectors dominated by "incremental" innovation, *i.e.*, by changes and additions to existing knowledge rather than by discrete innovations.

The introduction of an explicit research exemption for patents on plants has been recommended by experts in the United States, where it has been also suggested that all biological materials required for IPR protection become "part of the national germplasm system" (CCSA, 1993, p. 9).

In Mexico, the 1991 patent law (revised in 1994) provides for an explicit exception with regard to patents "relating to living materials". It states that the title-holder cannot prevent a third party from making use of the patented product, "as initial source of variation or propagation to obtain other products, except where such use was made previously" (article 22,V).

Compulsory licenses

A compulsory license is an authorization conferred by a relevant national body to use a patent without the consent of the patent-owner. Most countries provide some modalities of compulsory license, which are explicitly allowed by the TRIPS Agreement, which does not limit the grounds for the granting of compulsory licenses, but establishes the conditions under which the grant may take place (Correa, 1994b, p. 331).

Access to a patented material, and its use for research and breeding, if not otherwise ensured, may be obtained by means of compulsory licenses, if provided for by national legislation. Such licenses may be granted on grounds related to public interest, lack of exploitation of the invention, anti-competitive practices by the patent holder, emergency, or other reasons, including conservation or protection of the environment.

A very detailed provision on compulsory licenses grounded on the dependency of patents is contained in Article 31 (l) of the TRIPS Agreement. It contains a number of conditions for granting of compulsory licenses relating to the technical and economic importance of the "second patent" (which shall involve "an important technical advance of considerable economic significance"), the granting of "a cross license on reasonable terms" to the owner of the "first patent", and the non-assignability of the license (except with the assignment of the "second patent").

Dependent patents are particularly relevant in those areas in which innovation proceeds by incremental steps, by adaptation or improvement of pre-existing knowledge, rather than a discrete form. Plant breeding, as mentioned above clearly falls within this category. Starting from a patented plant variety, an improvement thereon by a third party may (if the patentability requirements are met) give raise to a dependent patent.

The problem is, however, that in order to improve a variety, the third party should be able to legitimately accede to the protected material, a possibility that the patent holder may restrict. The unauthorized use of the protected material, in the absence of an exception, as indicated above, may constitute infringement, and entail civil and criminal sanctions.

Since, as mentioned, the TRIPS Agreement does not limit the grounds for conferring compulsory licenses, national legislation may provide for such licenses as specifically required to ensure access to a patented material, in order to attain specific agricultural objectives (*e.g.*, availability of a given material for farmers) or food security, against a remuneration to be determined by the national authority.

Such licenses may also be available whenever the patent holder has not voluntarily accepted, having been requested to do so, to grant a license on reasonable commercial terms for the use of the patented plant material for improvement or the development of a new variety.

It should be recalled, finally, that Chapter 34 of "Agenda 21", provision 34.18, unanimously adopted at the Rio Conference, recommended the provision of compulsory licenses to facilitate access to and use of environmentally sound technologies.

Revocation of patents

The grounds for revocation/forfeiture of a patent have not been dealt with in the TRIPS Agreement. The single provision on this matter only obliges to ensure the availability of a judicial review of a decision to revoke a patent, but does not limit the grounds on which such a decision may be adopted.

If a patent, as determined by most laws, may be revoked because of the lack of payment of annual maintenance fees, among other reasons, nothing should prevent a WTO Member to cancel a patent if the applicant has not complied with or violated other applicable rulesA patent law cannot be viewed in isolation from the rest of the legal system. There is a need, in particular, to better articulate IPR legislation with the legal regimes that may be developed to implement the CBD provisions in certain areas.

For instance, in the case of materials that are not subject to a multilateral system as proposed under current negotiations in FAO, patent applicants may be requested to declare the country of

origin of biological materials related to the invention (what in practice applicants normally do) (UNEP, 1996, p. 13)[41].

III. Access under plant breeder's rights (PBR)

This subsection examines the extent to which PBR, as generally granted under UPOV-like legislation, affect the access to plant genetic resources for research and breeding. As examined elsewhere[42], there are important differences between the nature and modalities of patents and PBR protection, which help to understand why the access issue is substantially different under both regimes. Though such differences are not addressed here in detail, they should be borne in mind while analyzing how PBR affect access for research and breeding.

The compatibility of PBR legislation with a multilateral system based on a free access to PGR, was stated in FAO Conference Resolution 4/89, which adopted an "agreed interpretation" of the International Undertaking:

"Plant Breeders' Rights, as provided for under UPOV (International Union for the Protection of New Varieties of Plants) are not incompatible with the International Undertaking".

At the time of this Resolution, UPOV 1978 was in force. The question arises whether changes in legislation and, particularly the adoption of UPOV 1991, entail any substantial change with respect to the declared compatibility.

Scope of protection

PBR are exercised in respect of the propagating materials of the protected varieties[43], such rights do not cover the "process technology for the production of new varieties even where this is applicable to a wider range of plant materials than the individual variety of a particular species" (Crespi, 1988, p. 112).

By definition, PBR prevent third parties from using those materials for production or reproduction (multiplication) and related acts (conditioning for propagation, offering for sale, selling, importing/exporting, stocking), but do not protect the germplasm as such. Thus, PBR on a variety do not confer any specific rights with respect to certain genes or a combination of genes, which remain in the public domain for further research and breeding.

The PBR regime has traditionally included an exception for the use of a protected variety for the purposes of research and breeding, clearly including the commercial breeding of a new variety. This feature is common in PBR laws in developed and developing countries, including the most recent legislation on the matter (such as the legislation approved in the Andean Group in 1993; Mexico in 1996, and Brazil in 1997).

The "breeder's exemption" has also been recognized in the UPOV Convention, including the 1991 Act. In line with the Convention, the UPOV Model Law suggests a provision stating that the breeder's rights shall extend to acts done for "experimental purposes" and for "the purpose of breeding other varieties" (article 14 (ii) and (iii)).

Infringement

The subject matter protected under PBR is a *new* "plant variety" which meets DSU (distinctness, stability, uniformity) requirements. The criterion of distinctness can be seen not only as a condition for protection, but also as defining the borders of protection. A variety that is distinct from a protected variety, cannot infringe the latter; moreover, it may (if the other conditions are also met), obtain protection on its own right.

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41 A provision of this type is contained in Decision 391 (1996), which establishes the Andean Group regime on access to genetic materials.

42 See, for instance, Heitz, 1991, p. 19-22.

43 UPOV 1991 permits national legislation to extend the exercise of rights in respect of the harvested materials, if the title holder had not had the possibility of exerciing them with respect to the propagating materials.

Infringement will only exist[44] when any of the acts subject to the exclusive rights of the title holder is performed without his/her authorization with respect to:

* varieties which are not clearly distinguishable from the protected variety; and
* varieties whose production requires the repeated use of the protected variety.

As mentioned, under UPOV 1991, it is also an infringement to produce/reproduce and perform related acts with respect to "essentially derived varieties". The introduction of this concept, though seemingly aimed at avoiding "cosmetic" varieties, broadens the scope of protection conferred to the title-holder, and may limit the diffusion of varieties improved by farmers, though (if the farmers' privilege is recognized) would not prevent them from using the derived varieties in their own exploitations**.**

In sum, unlike patents, PBR do not restrict access to plant materials for research and breeding. National laws, and the UPOV Convention, specifically exclude research and breeding activities from the scope of the title-holder's rights. Though the concept of "essentially derived varieties" broadens the required "distance" with respect to a protected variety, the basic principle of free access to germplasm for developing **new** varieties remains an essential feature of the PBR regime.

Deposited materials

Under PBR laws, protected materials become available for research and breeding when commercialized by the title-holder or with his consent. UPOV-like legislation protects varieties on the market, and is generally opposed to access to any non-marketed deposited material. Non-marketed materials, thus, accumulate PBR and trade secrets protection. In this case, access is often granted under "material transfer agreements" for non-commercial purposes, subject to grant-back provisions. That may hinder future innovation on the material received (Houser, 1993, p. 109).

The accumulation of PBR and trade secrets does not seem to be, however, a necessary requirement in UPOV-type laws. As noted in a recent Seminar sponsored by the US Department of Agriculture and other entities,

> "there is no reason why a country adopting a UPOV-type system could not require that the deposits could be open, and this would give the choice to the plant breeder" (CSSA, 1998, p. 108).

IV. Access under the regime on undisclosed information

The breeder's exception does no cover materials that are held as confidential information by their legitimate possessor. This is particularly relevant in the case of hybrids. Since hybrid seeds need to be replaced for each cycle of production, because they do not breed true, such seeds are protected by their very nature against unauthorized reproduction. Though, under some PBR legislation, hybrids may be protectable, hybrid seed producers have often tended to keep secret the corresponding parent lines,[45] and have not sought formal protection under PBR. In some cases, the parent lines themselves may be, and have been, protected under PBR.

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44 See the UPOV Model Law, 1996.

45 The protection of inbred lines as a trade secret was explicitly recognized in the United States in the case of Pioneer Hi-Bred against Holden, in which the former was awarded $ 47 million as damages arising from the misappropriation of such lines by the latter.

The TRIPS Agreement obliges Member countries to protect undisclosed information of commercial value, provided that other specified requirements are met (Article 39). Hence, parent lines may be kept secret, and should, as a minimum, deserve the protection accorded under the Agreement. To the extent that the access to such lines is effectively restricted by secrecy, it will not possible for third parties to undertake improvement activities without the authorization of the possessor of the secret lines.

Unlike patents and other IPR, however, the protection of undisclosed information does not confer an *exclusive right*, but only the faculty to act in cases of dishonest commercial practices. The distinction is important, since it means that information and materials protected because they are secret may be used and reproduced by a third party, if such acts do not imply an unfair commercial practice: trade secrets law does not protect against discovery and use through independent development, accidental or wilful disclosure.

Moreover, under many laws (including in the United States), the *reverse engineering* of trade secrets is legitimate (Neff and Smallson, 1994, p. 102; Barton, 1998, p. 26). The same approach seems to have been followed by the TRIPS Agreement. According to its article 39.2 (b), in order to be protected, the "undisclosed information" must be "secret in the sense that it is not ... readily accessible to persons within the circles that normally deal with the kind of information in question" . Hence, to the extent that the secret can be discerned through evaluation of a product that "incorporates" it, no protection would be available.

Contractual clauses applied by seed companies in some countries have been reported to aim at preventing reverse engineering. Conditions of sale and label licenses on bags of seeds ("shrink wrap" licenses) are often very restrictive on the use of seeds (CSSA, 1998, p. 115), imposing restrictions beyond those determined by the applicable substantive laws.

In sum, the extent to which trade secrets protection may restrict access for research and breeding will depend on the rights conferred on the possessor, in respect of acts of reverse engineering, when the information is "embodied" in and obtainable from the products, and, eventually, on the terms and conditions of the respective sales contract. In the case of parent lines, if they are used to produce hybrids and are not commercialized as such, the legal protection creates a barrier against the unauthorized access to, and use of, such lines for further research and breeding.

V. Conclusions

Access to PGR for food and agriculture for research and breeding is an essential element in any possible multilateral system on the conservation and exchange, including benefit sharing, of such resources. Concerns have been voiced both in developing and in developed countries with regard to the extent that IPR may restrict such access.

The analysis made has shown the implications of three types of IPR (patents, PBR, undisclosed information) on the access to protected materials for research and breeding. Patents are currently granted in some countries in respect of genes, plant varieties and other plant materials, as well as of processes for their manipulation.

Patents on isolated genes, generally claimed jointly with vectors, and modified cells and plants, permit the control of the use of the genes by genetic engineering, but should not block, in principle, the use of the original gene in its natural form in conventional breeding, though this has still to be tested through litigation. The acceptance of broad claims, the uncertainty about the limits of the patent-holder's rights, and the aggressive enforcement of patent rights, may, however, limit research and breeding activities. Clear rules that establish, at national and international level, that, despite the patenting of isolated genes, they remain "free to all men and reserved exclusively to

none",[46] may contribute to dissipate current concerns on the implications of this type of patents for research and breeding.

In some jurisdictions, plant varieties are also eligible as patent subject matter. Protection of this sort, in the absence of adequate exceptions for experimentation, may effectively block access to the patented material as a source of further variation.

In the framework of the international standards in force on patent protection, as determined by the TRIPS Agreement, various types of provisions and exceptions may be introduced in national laws, in order to ensure access to patented plant materials, for research and breeding. On the one hand, patent grants on any classification of plants and parts thereof, may be excluded by national laws. On the other, several options exist to deal with issues, such as the admissible scope, and the interpretation of claims, access to the deposited material, the "experimentation" exception, the granting of compulsory licenses, and the revocation of patents. Adequate provisions on these issues may also contribute to ensuring access to plant genetic resources for research and breeding.

Unlike patents, PBR contain a clear research and breeding exception. Though the scope of the exception may be limited by the notion of "essentially derived varieties", the PBR system does not seem to create barriers for access to protected materials for research and breeding and, in this regard, seems compatible with the objectives of a multilateral system for the shared access to PGR for food and agriculture.[47]

Finally, the protection of plant materials as undisclosed information may limit access, but it neither creates exclusive rights, nor prevents, in principle, the reverse engineering of products legitimately put on the market. The compatibility of this form of protection with a multilateral system on plant genetic resources for food and agriculture, is acknowledged, within the framework of the International Undertaking.

In sum, the extension of IPR on plant materials does give raise to a number of issues relating to access to PGR for research and breeding, which may be addressed at national level, as well as by clarifying some on the international rules applicable on the matter, notably on the effects of patents on genes, and on the admissibility of an "experimentation" exception in respect of plant patented materials.

Based on the above analysis, and having in view the development and future implementation of a multilateral system on PGR for food and agriculture under a revised International Undertaking, a number of conclusions for action at the international level may be drawn, namely to:

a) preserve the right of any country, as currently recognized under the TRIPS Agreement, to exclude plants and any parts thereof, including DNA sequences, from patentability;

b) adopt clear rules indicating that natural occurring plant materials, including genes, are and shall remain outside any IPR protection in any country;

c) define the novelty requirement in a manner that excludes the patentability of any subject matter which was made available to the public, by means of a written description, by use or in any other way,[48] in any country before the date of filing, including use by local and indigenous communities, and deposit of a material in a germplasm bank or other deposit institution where such material is publicly available;

d) establish commitments by governments not to grant, or to cancel *ex officio*, or upon request, IPR on plant materials obtained from collections held in international germplasm banks and other deposit institutions where such materials are publicly available, or in violation of other applicable rules.

e) specifically provide for the right of any country to allow an experimentation exception (including research and breeding), in the case that patents are granted on plant materials, including plant varieties.

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46 A provision on this issue may be considered in an eventual revision of the TRIPs Agreement (article 27.3 (b)).

47 Other implications of PBRs, notably those arising from the uniformity requirement, are dealt with separately.

48 See article 54.2) of the European Patent Convention.

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